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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/089,147	03/27/2002	Helmut Kindl	50815	9820

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EXAMINER	
PAK, YONG D	

ART UNIT	PAPER NUMBER
1652	

DATE MAILED: 03/08/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/089,147	KINDL ET AL.	
	Examiner	Art Unit	
	Yong D Pak	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-55 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-55 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-55 are pending.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-18, 21-23, 26-28, 31-37 and 44, drawn to DNA encoding a monooxygenase of SEQ ID NO:8, 10, 12, 18, 22, 24, 26, 28, 30, 32, 34, 36, 38, 40, 42, 44 or 46-49 and host cell comprising thereof, classified in class 435, subclass 252.3.

II. Claims 19-20, 24-25 and 29-30, drawn to a monooxygenase of SEQ ID NO:8, 10, 12, 18, 22, 24, 26, 28, 30, 32, 34, 36, 38, 40, 42, 44 or 46-49, classified in class 435, subclass 189.

III. Claims 38-39 and 42-43, drawn to a method of obtaining DNA encoding a monooxygenase using the DNA of Invention I, classified in class 435, subclass 6.

IV. Claims 40-41, drawn to a method of identifying a monooxygenase of Invention II, classified in class 435, subclass 7.4.

V. Claims 45-47, drawn to an in vivo transformation of a ketone to its corresponding ester using the DNA of Invention I, classified in class 435, subclass 135.

VI. Claims 48-50, drawn to an in vitro transformation of a ketone to its corresponding ester suing the DNA of Invention I, classified in class 435, subclass 135.

VII. Claims 51, drawn to a mutant gene made from the DNA of Invention I, classified in class 536, subclass 23.1.

VIII. Claims 52-54, drawn to a 16s rDNA of SEQ ID NO:1, 5 or 6 , classified in class 536, subclass 23.1.

IX. Claim 55, drawn to a DNA useful for the identification of a monooxygenase selected from the group consisting of SEQ ID NO: 70-113, classified in class 536, subclass 23.1.

Applicants are required to elect ONE DNA sequence encoding a monooxygenase and/or ONE monooxygenase sequence of Inventions I-VI. If Invention VIII is elected, applicants are required to elect ONE 16s rDNA sequence. If Invention IX is elected, applicants are required to elect ONE DNA sequence.

This is not an election of species. The nucleic acid molecules and the monooxygenase of Group II are independent chemical entities and require independent search in the patent and non-patent literature. Also, the nucleic acid sequence of SEQ ID NOs: 70-113 are independent chemical entities and require different searches.

The inventions are distinct, each from the other because of the following reasons:

Inventions I-II and VII-IX are patentably distinct because a DNA and a protein are different compounds, each with its own chemical structure and function, and they have different utilities. The DNA sequences of Inventions I are patentably distinct as encoding enzymes with different structures, functions, substrate specificities, and utilities. The proteins of Inventions II are patentably distinct as having different structures, functions, substrate specificities, and utilities. The 16s rDNA sequences of Invention VIII are patentably distinct from each other because the have different structure, physical and chemical properties/characteristics and utilities. The DNA sequences of Invention IX are patentably distinct from each other because the have different structure, physical and chemical properties/characteristics and utilities.

The DNA molecules of invention I is not limited in use to the production of polypeptide of invention II, respectively, and can be used as a hybridization probe, and protein of Invention II can be obtained by a materially different method such as by biochemical purification.

Inventions I and (III and V-VI) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the DNA of Inventions I can be used for the production of the protein of Invention II.

Inventions II and (IV) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the

process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the protein of Invention II can be used for the production of the antibodies against the protein.

The methods of Inventions III-VI are patentably distinct as directed to materially different methods employing different products. Inventions III and V-VI uses DNA, Invention IV use polypeptides.

The methods of III and V-VI are patentably distinct because the methods have different effects and utilities. Inventions V-VI are patentably distinct because Invention V is an in vivo method and Invention VI is an in vitro method.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is

subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yong Pak whose telephone number is 703-308-9363. The examiner can normally be reached on 8:00 A.M. to 4:30 P.M weekdays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on 703-308-3804. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Yong Pak
Patent Examiner

March 4, 2004

NASHAAT T. NASHED PHD.
PRIMARY EXAMINER